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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jan Weber

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EXAMINER

MCEVOY, THOMAS M

ART UNIT

PAPER NUMBER

3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,825	Applicant(s) WEBER ET AL.	
	Examiner THOMAS MCEVOY	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 30-63, 65, 66 and 69-87 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-13, 15, 16, 24, 25, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 60, 61, 63, 71-74, 80-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/20/05, 6/17/04, 5/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,8,14,17-23,26,27,33,39-49,51,53,55,58,59,62,65,66,69,70 and 75-79.

DETAILED ACTION

1. This Office Action is in response to the Request for Continued Examination received on September 25, 2007. The addition of new claims 85-87 is acknowledged.

Examiner Note

2. The prosecution history for this application shows that an Advisory Action was sent to the Applicant by the Office on September 27, 2007. Please note that this Advisory Action has been vacated and no further action is required by the applicant in response to it, only a response to this Office action is required as set forth in the Office action summary.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims **1-3, 5, 6, 9, 12, 13, 15, 24, 25, 61 and 80** are rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (US 6,514,237) for the reasons previously made of record.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims **4, 10, 11, 16, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 60, 61, 63, 71-74 and 80-86** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237). Claims 10 and 11 are rejected for the reasons previously made of record. Claims 4, 16, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 60, 61, 63, 71-74 and 80-86 are rejected for the reasons discussed below.

Regarding claims 4, 10, 11, 16, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 60, 61, 63, 71-74 and 80-86, Maseda teaches that the medical device (as explained in the previous record and with further explanation) contains one or more active regions (or electrically actuated members), each comprising a series of circumferentially spaced strands (or circumferential band), where the strands are electroactive polymers and conductive (and an electrode or counter electrode; column 5 – lines 7 to 8) (and can also be considered as active regions depending on the limitations) and disposed over an elongate body such that the medical device is expanded in at least one radial dimension relative to the longitudinal axis of the elongate body upon expansion (or volumetric

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expansion, depending on the definition of the active region) of the active region in order to expand difficult-to-pass passageways (much like a balloon catheter) (tube 114 or a portion of tube 114 is disposed over tube 116; figure 5A; column 4 - lines 18 to 21; column 6 - lines 38 to 62). Maseda further teaches that the strands may be incorporated into various segments (or any segment) of the device so that the device expands like and mimics a balloon in a balloon catheter (column 3 - lines 3 to 6), that the circumferential band of composite strands expands and functions like a balloon (column 6 – lines 47 to 59), and that the balloon itself may incorporate the composite strands (column 8 – lines 6 to 9).

Maseda does not teach: a balloon or passive deformable region where the proximal, central and/or distal portions expand radially due to volumetric expansion of the active region beneath it and thus radially expand a lumen which is in fluid communication with the balloon.

It would be obvious to one of ordinary skill in the art, having the teachings of Maseda before him or her at the time the invention was made to have incorporated the circumferential band of strands into a balloon structure, as suggested by Maseda, in order to provide more control over expansion and contraction of the balloon (a benefit that is readily apparent from the combination), and incorporate the strands either within the elastic balloon or directly beneath the balloon as either orientation would be an obvious design choice and provide similar or identical results. Further, the active region, comprising the strands or a single strand (depending on the claim of the instant application that is being compared) and being a counter electrode to the power source,

would be enclosed by the balloon along with the balloon inflation solution ;where the electrolyte saline is notoriously well known for inflating balloon catheters and would be also be an obvious design choice for inflating the balloon.

8. Claim **87** is rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (US 6,514,237) in view of Sharrow (US 4,793,359).

Regarding claim 87, Maseda teaches the invention as described above comprising a plurality of active regions, where an active region can be one of the strands described above in regards to claim 28.

Maseda fails to teach: the medical device of claim 28 comprising a plurality of said active regions wherein a first active region is disposed over a first conductive radio-opaque band and wherein a second active region is disposed over a second conductive radio-opaque band that is positioned distal to said first conductive radio-opaque band.

Attention is drawn to Sharrow who teaches that a balloon in a balloon catheter can have two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon (column 4 - lines 4 to 5).

Therefore, it would be obvious to one of ordinary skill in the art and having the teachings of Maseda and Sharrow before him or her at the time the invention was made to have incorporated two conductive (metal) radio-opaque bands positioned at either end of the interior of the balloon to confirm the dilating length of the balloon.

Response to Arguments

9. Regarding claims **1, 5, 10, 73** and **74**, Applicant's arguments filed on September 25, 2007, which incorporate arguments previously made of record, have been fully considered but they are not persuasive.

Regarding claim 1, Applicant argues that one of ordinary skill in the art would recognize that a conductive polymer and an ionic exchange polymer-noble metal composite are in separate classes of electroactive polymers and therefore the later would not be confused with the former by one of ordinary skill in the art when reading the claim. Applicant agrees with the fact that in the field of polymer chemistry or electro-chemistry or even the broader field of chemistry, one of ordinary skill would not confuse the polymers in the interpretation of the claim. However, Examiner asserts that the invention as a whole is directed to anyone of ordinary skill in the medical device art and possibly even the much broader medical art where the terms in question would most likely not be recognized as separate classes of polymers and that the term "conductive polymer" would be interpreted very broadly; possibly encompassing any polymer which is electrically conductive. Applicant further argues that the active region of the Maseda reference does not undergo volumetric expansion because the ionic exchange polymer-noble metal composites are incapable of such. Examiner agrees that the polymer of reference does not undergo volumetric expansion but is arranged to form an active region which undergoes volumetric expansion. Examiner directs attention to the claim language which states that the active region comprises a conductive polymer, therefore the

conductive polymer does not necessarily need to undergo volumetric expansion to be embodied by the claim. Furthermore, the term 'active region' as written, is very broad and encompasses not only physical structures but also non-physical sections or functional elements which can be identified as a region of the medical device.

Regarding claim 5, Applicant argues that the active region of the Maseda reference does not take the form of a circumferential band. Examiner believes that under the broadest reasonable interpretation of the term as written, with no further description claimed, a 'circumferential band' is not inherently a unitary structure and would embody a circumferentially spaced series of strands which form a distinct functional structure and surround an interior structure; which the active region of the Maseda reference comprises.

Regarding claim 10, Applicant argues that the active region is not disposed in a circumferential recess in the elongate body of the medical device. Examiner refers to Figure 5 and column 6 - lines 38 to 41 where Maseda discloses that the active region can take the form of circumferentially spaced strands formed from a section of tube 114 (which is a part of the elongate body) and thus would necessarily form and be disposed within a recess; noting that tube 116 is disclosed to be beneath tube 114.

Regarding claims 73 and 74, Applicant states that the response of record to previous arguments does not make the claim limitations obvious. Examiner redirects attention to the response above regarding claim 1, where it is noted that

the active region expands volumetrically which is also radially. Examiner refers to column 6 - lines 1 to 2 of the Maseda reference where it is disclosed that the electroactive polymers are stiffened under applied voltage, therefore at least a portion of the active region would be stiffened as well. Examiner also refers to column 3 – lines 50 to 55 of the Maseda reference which discloses that the electroactive polymers can be configured to elongate the medical device. Therefore, where the active region is deemed to be any functional element of the device comprising the electroactive polymer which causes stiffening and expansion in the longitudinal direction as claimed in claims 24 and 74, the arrangement of the electroactive polymers which causes the device to elongate must also be elongated longitudinally.

10. Applicant's arguments in regards to claims **4, 16, 28, 50, 60, 71, 72, 81-83**, and corresponding dependent claims, filed on September 25, 2007, which incorporate arguments previously made of record, have been fully considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 7:30-5:00 (alternate Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4123